Inordinate delay in handling applications in DCI office

2166. SHRI CHO. S. RAMASWAMY : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) the total number of applications received per month in the DCI office for various categories of approvals required from this office;

(b) the time taken for clearance of application;

(c) whether it is a fact that many cases take a lot of time for clearance from the Department;

(d) the steps being taken to streamline the system of this office;

(e) whether it is a fact that NOC for exports take a long time for clearance causing cancellation of export orders; and

(f) if so, the reasons therefor ?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THANKUR) : (a) Office of DCG(I) receive various categories of application which pertain to issue of test license in Form 11, import license for Sch. C or C-1 drugs and diagnostics under Form 10, approval and market authorization for manufacture/import of new drugs, clinical trial approval, new formulations, new drug delivery systems. No Objection Certificates for export of unapproved and banned drugs, approval of licenses for manufacture of vaccines, Large Volume Parenterals blood banks/blood products etc. monthly receipts of such applications, therefore, varies.

(b) and (c) The time taken for clearance of such application depends upon the nature of examination required in respect of specific products and the extent of relevant documents submitted by the applicants. Test licenses in Form 11 are usually issued within 2 weeks and import license in Form 10 within a month. In certain cases where information relating to test protocol, cold chain methodology, stability studies etc. are further required, disposal of applications may take some more time. Evaluation of new drugs applications is a complex process, Time taken, therefore, varies according to nature of the molecule/drug, trial to be performed by the applicant and testing by CDL etc. This involves 1—3 years for first time approval of the drug marketed elsewhere and 2-3 months for subsequent application.

Within the constraints of infrastructure etc. different categories of applications are being processed without inordinate delay.

(d) The detailed format mentioning requisite documents has been issued to all concerned for proper filing of applications in respect of import licenses and NOCs for experts. Rules pertaining new drugs are being amended to prescribe specific application formats and evaluation fee etc. For new Melecules and DNA derived products, expert penels have been constituted for multi-disciplinary examination. Finance Ministry has been approached to sanction additional posts as well as to revive the lapsed posts of CDSCO.

(e) and (f) NOCs for export are to be issued for manufacture of unapproved and banned drugs as per the procedure prescribed by the Government under direction of the Supreme Court. Many times the applicants do not furnish all required information and correspondence is to be held with them. However, on an average, most of the applications are being disposed within 3 weeks.

Tenure of stay in CGHS Medical Store Depots

2167. MAULANA OBAIDULLAH KHAN AZMI : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :

(a) whether a certain tenure of stay was fixed for staff working in CGHS Medical Store Depots in Delhi/New Delhi as these depots were considered "Corruption Prone Zone";

(b) if so, the tenure of stay fixed for each category of officials posted there;

(c) the names of officials, with the tenure of their stay, in these depots during the last six years;

(d) whether it is a fact that certain officials are transferred for a short spell and posted again to Medical Store Depots; and

(e) if so, the action proposed to be taken to rectify the situation ?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THANKUR) : (a) and (b) A period upto 3 years has been fixed as tenure of stay in respect of Group 'C' and Group 'D' staff working in CGHS Medical Store Depot. However, some officers have stayed for longer periods due to administrative exigencies.

(c) The information is given in the Statement (*See* below)

(d) No, Sir.

(e) In view of (d) above, the question does not arise.